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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/271,098	03/18/1999	REY T. CHERN	20023Y	3620

210 7590 11/05/2002

MERCK AND CO INC
P O BOX 2000
RAHWAY, NJ 070650907

EXAMINER

SHARAREH, SHAHNAM J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 11/05/2002

28

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/271,098

Applicant(s)

CHERN ET AL.

Examiner

Shahnam Sharareh

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 27.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Amendment filed on August 13, 2002 has been entered. Claims 1-15 are pending. Any rejection that is not addressed in this Office Action is considered obviated.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Applicant's arguments filed August 13, 2002 have been fully considered but they are not persuasive for the reasons set forth below.
4. Claims 13-14 stand rejected under 35 U.S.C. 102(b) as being anticipated by Damani et al US Patent 5,447,725 (Damani).

Applicant argues that Demani does not utilize various drugs that are now limiting the formulation of claims 13-14 (see page 4 of the Amendment).

In response Examiner states that contrary to Applicants contention, the instant claims are directed to such formulations comprising non-steroidal anti-inflammatory drugs such as naproxen, ibuprofen, flurbiprofen and indomethacin (see col 6, lines 17-21; col 7, lines 5-44). Accordingly, Demani anticipates the limitations of the instant claims for the reasons of record.

5. Claims 1-14 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Broadbeck US Patent 6,130,200 in view of Tipton et al US Patent 5,792,496 or Tipton in view of Broadbeck.

Applicant argues that neither of the cited references teaches the use of active agents set forth in the instant independent claims 1 and 13. Applicant appears to be arguing against the references individually, however, one cannot show nonobviousness

Art Unit: 1617

by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Here the combined teachings of the cited references teaches all elements of the instant claims. For example, Broadbeck clearly teaches the use of various active agents such as erythromycin (a macrolide), ibuprofen (a non steroidal anti inflammatory) (see col 20, lines 10-24). Furthermore, Broadbeck teaches that modification of a solvent system wherein the solvent is substantially water immiscible would control the rate of water migration into the polymer implant thus control the delivery of a therapeutic agent of choice (see col 8, lines 61-67; col 10, lines 40-60, see figures 4-5, table 2).

Broadbeck only fails to teach compositions wherein the concentrations of polymeric moiety are in amount lower than 10% w/v.

This limitation is taught by Tipton. Tipton specifically teaches lower concentrations of his polymeric moiety in amount of about 5% -10 % w/v (see all examples of Tipton col 13-16). Tipton also provides that suitable solvent mixtures and additives can be used to modify the rate of coagulation or solidification of their composition, as well as, their drug release properties (see col 6, lines 49-62; col 10, lines 25-48). However, Tipton fails to specifically teach a solvent mixture wherein the hydrophilic and lipophilic ratio is from about 65:35 to about 5:95.

Applicant further argues that a *prima facie* obviousness rejection requires a showing of motivation, not routine experimentation (see page 5 of the Amendment). In response, Examiner recognizes that obviousness can only be established by combining

Art Unit: 1617

or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Tipton attests to the general knowledge in the art that using lower concentration of polymeric provides desirable drug release properties. Accordingly, motivation is properly shown. Subsequently, given the motivation in the art to use lower concentrations of polymeric moiety, one of ordinary skill in the art at the time of invention would have been able to optimize a workable range by routine experimentation (see MPEP 2144.05 II).

New Grounds of Rejection

6. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Broadbeck in view of Tipton as applied to claims 1-14 above, and further in view of Lewis US Patent 5,733,566 (IDS, Paper No. 4, page 10/10).

The combined teachings of Broadbeck and Tipton have been described above. Broadbeck and Tipton fail to particularly use ivermectin as a suitable antiparasitic agent.

Lewis teaches the use of antiparasitic agent in injectable polymeric compositions wherein the amounts of antiparasitic agent are about 29%-55% weight of the composition. Moreover, Lewis suggests the use of ivermectin, as an antiparasitic, in polymeric moieties where the polymeric moiety comprises poly (lactide co glycolide) in ratios of about 55:45-75:25 (see col 15, line 21; col 17, lines 15-31). Lewis does not explicitly use a mixture of hydrophilic and lipophilic solvent.

Nevertheless, as taught by Broadbeck, using a hydrophilic, lipophilic solvent system improves the delivery of the active agent. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use a mixed solvent system of Broadbeck with polymeric moieties of Tipton, as described above, in delivering an antiparasitic agent such as ivermectin, as taught by Lewis, because the ordinary artisan would have had a reasonable expectation in enhancing the delivery of the such agent in a site of interest.

Conclusion

No claims are allowed. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh, PharmD whose telephone number

Art Unit: 1617

is (703) 306-5400. The examiner can normally be reached on Monday to Friday from 8:30 a.m. to 5:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Padmanabhan Sreenivasan can be reached on 703-305-1877. The fax phone number for this Group is 703-308-4556. Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is 703-308-1235.

RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200